K123460

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510(k) SUMMARY

TOPCON TRC-NW300 Non-Mydriatic Retinal Camera

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: February 1, 2013

Name of Device and Name/Address of Sponsor
Topcon TRC-NW300 Non-Mydriatic Retinal Camera
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

Common or Usual Name
Retinal Camera

Classification Name
Camera, Ophthalmic, AC-Powered
21 C.F.R. 886.1120
Product Code: HKI

K123460

Predicate Devices
Topcon Medical Systems TRC-NW200 (K041367)
Topcon Medical Systems TRC-NW8F (K100207)

Intended Use

The TRC-NW300 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without the use of a mydriatic.

Device Description

The Topcon TRC-NW300 is a fundus camera designed to observe, photograph and record the fundus oculi of a patient's eye with or without the use of a mydriatic. The TRC-NW300 does not come into contact with the patient's eye and provides the fundus oculi image information as an electronic image for later analysis.

The TRC-NW300 houses a color LCD monitor used for observation and display of a photographed image and a digital photography unit used for recording images. A photographed image may be recorded on a commercially available memory card inserted in the memory card slot of the TRC-NW300, to a commercially available image filing system, or on a commercially available storage device (such as a flash memory, a hard disk or a card reader/writer) connected to the TRC-NW300. A photographed image may also be printed on a commercially available digital printer connected to the TRC-NW300.

Performance Data

The TRC-NW300 has been tested and found in compliance with the following recognized consensus standards:

IEC 60601-1:1988 +Amd 1: 1991 + Amd 2: 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety;

IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;

ISO 15004-1:2006 Ophthalmic Instruments-Fundamental requirements and test methods-Part 1: General requirements applicable to all ophthalmic instruments;

ISO 15004-2:2007, Ophthalmic Instruments-Fundamental requirements and test methods-Part 2: Light hazard protection.

Additionally, design verification tests were performed as a result of the risk analysis assessment. These test results demonstrated that the TRC-NW300 met predetermined acceptance criteria.

Technological Characteristics and Substantial Equivalence

The TRC-NW300 has very similar technological characteristics as the TRC-NW200, to which it is a modification. The overall principle of operation of the TRC-NW300 is unchanged compared to the previously cleared TRC-NW200. Both devices illuminate the fundus oculi using infrared light emitted from the illumination optical system and present an image of the fundus oculi formed on the observation CCD camera housed in the main unit to the color LCD monitor. Both devices have a built in camera for photography and a built in camera for observation. Both devices have a color LCD monitor for observation. The observation light source and the photography light source are the same in both devices. Additionally, both devices have an infrared filter for retinal observation that can be removed from the optical path. Thus, the TRC-NW300 is the same device as the TRC-NW200 except for the following modifications:

- TRC-NW300 incorporates the capability to use a USB Memory Card or an external digital printer
- TRC-NW300 had a different diaphragm design which allows photography of patients with pupils as small as 3.3 mm
- TRC-NW300 incorporates an 8 mega pixel CCD Camera vs. a 3.15 mega pixel CCD Camera in the TRC-NW200
- TRC-NW300 incorporates an automatic focusing function
- TRC-NW300 changes the position of internal fixation targets
- TRC-NW300 employs an automatic flash (capture) function (when the camera is in the proper position)
- TRC-NW300 has the capability to use alpha as well as numeric patient identification characters

- TRC-NW300 includes an automatic small pupil detection system
- TRC-NW300 includes an illumination system for the control panel
- TRC-NW300 utilizes a motorized chinrest mechanism
- TRC-NW300's power supply's normal power has increased from 80 VA to 100 VA
- TRC-NW300 includes minor changes to the physical dimension of the device

Each of these modifications was evaluated by Topcon to determine if they could affect the safety or effectiveness of the device and it was determined that they do not. Additionally, the vast majority of these new features have already been cleared by the Agency in the Topcon TRC-NW8F Retinal Camera (K100207). Design verification tests were performed as a result of a risk analysis assessment and demonstrated that the TRC-NW300 met predetermined acceptance criteria.

The TRC-NW300 has the same intended use and similar indications, principles of operation, and technological characteristics as the TRC-NW200 and the TRC-NW8F. The minor differences in the TRC-NW300's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the TRC-NW300 is as safe and effective as the TRC-NW200 and the TRC-NW8F. Thus, the TRC-NW300 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 6, 2013

Topcon Medical Systems, Inc.
% Ms. Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K123460
Trade/Device Name: Topcon TRC-NW300 Non-Mydriatic Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: November 8, 2012
Received: November 9, 2012

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123460

Device Name: TRC-NW300

Indications for Use:

The TRC-NW300 intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, without the use of a mydriatic.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K123460